Title 16. Respiratory Care Board
Department of Consumer Affairs

[Home Respiratory Care]

INITIAL STATEMENT OF REASONS

HEARING DATE: October 3, 2006

SUBJECT MATTER OF PROPOSED REGULATIONS:
This proposal will provide guidance to the home care industry, of what services a “delivery driver” or other unlicensed personnel may perform and under which criteria, as it relates to respiratory care and respiratory care related services.

SECTIONS AFFECTED:
Sections 1399.302 and 1399.360 of the California Code of Regulations, Title 16, Division 13.6, Articles 1 and 6.

SPECIFIC PURPOSE OF EACH ADOPTION, AMENDMENT, OR REPEAL:
Amend Section 1399.302 of Article 1 of Division 13.6 of Title 16 of the California Code of Regulations to: amend the definition of “employer” to include any company, corporation, partnership, health maintenance organization, or any other entity or person that employs or contracts with one or more respiratory care practitioners or unlicensed or unauthorized personnel to provide respiratory care services as provided in the Respiratory Care Practice Act; define “Home Care Employer”; and define “Unlicensed or Unauthorized Personnel.”

Adopt Section 1399.360 of Article 6 of Division 13.6 of Title 16 of the California Code of Regulations to specify what services, and under what criteria, respiratory care services may be performed by unlicensed personnel in a home care setting.

FACTUAL BASIS:
The Respiratory Care Board of California (Board) is mandated to protect the public from the unauthorized and unqualified practice of respiratory care and from unprofessional conduct by persons licensed to practice respiratory care. It is further mandated that "protection of the public shall be the highest priority for the Respiratory Care Board of California in exercising its licensing, regulatory, and disciplinary functions."

As health care delivery continues to advance and efforts to control healthcare costs continue, more patients are being cared for at home or at other non-clinical places for their convalescence. Many of the patients (ranging from newborns to the elderly) rely on medical devices for treatment or to sustain life. There is a broad range of capabilities and limitations in the population of potential medical device users and their caregivers. Limitations are both cognitive and physical.

In 2001, the Respiratory Care Board of California underwent a review by the Joint Legislative Sunset Review Committee and noted its concern for the lack of regulatory oversight for respiratory care provided in the home. In response, recommendations made by the Joint Committee included their support as well as the California Department of Consumer Affairs' support for the Board's effort to review this matter.

In 1987, legislation (1997 statutes, ch. 1115) passed which required all Medical Device Retailers to become licensed by California's Board of Pharmacy no later than July 1, 1991. Nine years later, in 2000, legislation (2000 statutes, ch. 837, AB 1496) passed which transferred the regulatory control

of Medical Device Retailers from the Board of Pharmacy to the Department of Health Services effective January 1, 2002. This legislation also expanded the regulatory oversight to include dispensing of oxygen, hospital beds and wheelchairs. Thus, a new licensure category, Home Medical Device Retail Facilities (HMDRF), was created. However, the regulatory oversight of HMDRF does NOT include the regulation of patient care. There is no requirement or inspection to evaluate competency or consider personnel qualifications as it relates to the care or well being of the patient.

In California, “home medical device” is defined in the Health and Safety Code, section 109948.1, subdivision (b) as "a device intended for use in a home care setting including, but not limited to, all of the following:

(1) Oxygen delivery systems and prefilled cylinders.
(2) Ventilators.
(3) Continuous Positive Airway Pressure devices (CPAP).
(4) Respiratory disease management devices.
(5) Hospital beds and commodes.
(6) Electronic and computer driven wheelchairs and seating systems.
(7) Apnea monitors.
(8) Low air loss continuous pressure management devices.
(9) Transcutaneous Electrical Nerve Stimulator (TENS) units.
(10) Prescription devices.
(11) Disposable medical supplies including, but not limited to, incontinence supplies as defined in Section 14125.1 of the Welfare and Institutions Code.
(12) In vitro diagnostic tests.
(13) Any other similar device as defined in regulations adopted by the department.

Some medical devices such as hospital beds and commodes require simple instruction and education and can be used easily and intuitively by many people with little or no difficulty. Failure to properly use or failure of such medical devices would rarely cause patient harm.

However, many sophisticated medical devices used for respiratory care such as ventilators, continuous positive airway pressure devices, respiratory disease management devices, apnea monitors and low air loss continuous pressure management devices, require extensive education and instruction or the consequences can be fatal. The use of these respiratory care devices is governed by the Respiratory Care Practice Act and requires licensure as a respiratory care practitioner, other qualified licensed personnel, or by a person exempted from the Act. Self-care by the patient or the gratuitous care by a friend or member of the family is one of those exemptions.

Unlicensed personnel employed by many HMDRFs are dispensing sophisticated devices and then providing care by adjusting settings as prescribed and providing consultation to the family to not only include how the machine operates, but also in reference to treatment of the patient. There are also numerous reports of fraud emerging specifically that HMDRFs are ordering additional tests without a physician’s order and billing for additional and unnecessary equipment. Many HMDRFs have been using equipment delivery personnel to conduct these respiratory diagnostic tests which are the basis for renting additional equipment.

The Board recognizes that in addition to providing comfort to patients, home care is also used to control health care costs. While the Board has already begun to address the unlicensed practice of respiratory care, it also recognizes that some basic and minor respiratory services may be provided safely by unauthorized personnel, under certain criteria. The Board has examined many of the respiratory tasks that are performed in home care and supports the proposed legislative amendments as a means to exempt certain respiratory tasks that may be performed safely under certain conditions by unlicensed personnel.

UNDERLYING DATA: None.

BUSINESS IMPACT: Insignificant.

SPECIFIC TECHNOLOGIES OR EQUIPMENT: None necessary.

CONSIDERATION OF ALTERNATIVES: No alternative which was considered would be either more effective than or equally as effective as and less burdensome to affected private persons than the proposed regulation.